US009180021B2

(12) **United States Patent**
Curran et al.

(10) **Patent No.: US 9,180,021 B2**
(45) **Date of Patent: *Nov. 10, 2015**

(54) **SYSTEMS AND METHODS FOR SPINAL FUSION**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/314,823**

(22) Filed: **Jun. 25, 2014**

(65) **Prior Publication Data**

US 2014/0309742 A1 Oct. 16, 2014

Related U.S. Application Data

(63) Continuation of application No. 14/171,484, filed on Feb. 3, 2014, now Pat. No. 8,814,940, which is a continuation of application No. 14/066,285, filed on Oct. 29, 2013, now Pat. No. 8,685,105, which is a

(Continued)

(51) **Int. Cl.**
A61F 2/44 (2006.01)
A61F 2/46 (2006.01)

(52) **U.S. Cl.**
CPC ***A61F 2/4455*** (2013.01); ***A61F 2/442*** (2013.01); ***A61F 2/447*** (2013.01); ***A61F 2/4611*** (2013.01); *A61F 2/44* (2013.01)

(58) **Field of Classification Search**
CPC A61F 2/4455; A61F 2/447; A61F 2/4611
USPC 623/17.11–17.16
See application file for complete search history.

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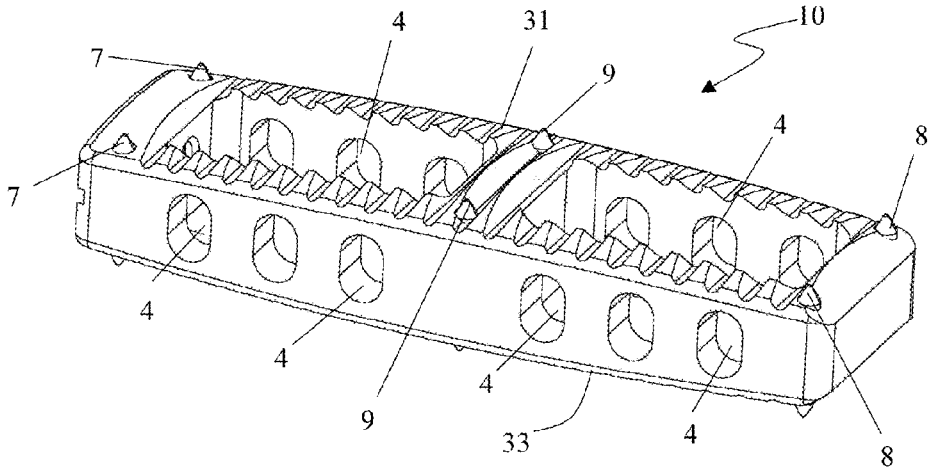
(57) **ABSTRACT**

A system and method for spinal fusion comprising a spinal fusion implant of non-bone construction releasably coupled to an insertion instrument dimensioned to introduce the spinal fusion implant into any of a variety of spinal target sites.

37 Claims, 20 Drawing Sheets



Related U.S. Application Data

continuation of application No. 13/748,925, filed on Jan. 24, 2013, now Pat. No. 8,574,301, which is a continuation of application No. 13/747,765, filed on Jan. 23, 2013, now Pat. No. 8,608,804, which is a continuation of application No. 13/441,092, filed on Apr. 6, 2012, now Pat. No. 8,361,156, which is a continuation of application No. 13/440,062, filed on Apr. 5, 2012, now Pat. No. 8,246,686, which is a continuation of application No. 13/079,645, filed on Apr. 4, 2011, now Pat. No. 8,187,334, which is a continuation of application No. 11/093,409, filed on Mar. 29, 2005, now Pat. No. 7,918,891.

(60) Provisional application No. 60/557,536, filed on Mar. 29, 2004.

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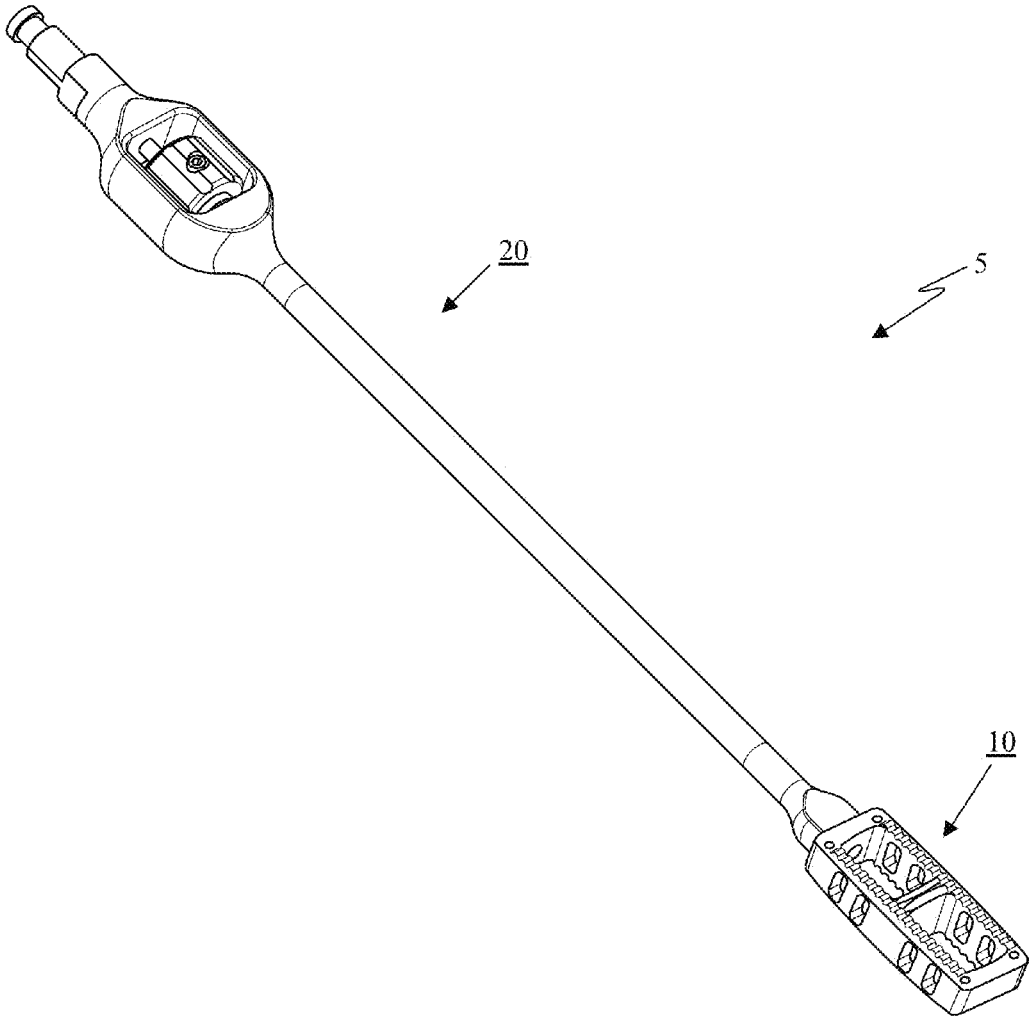


FIG. 1

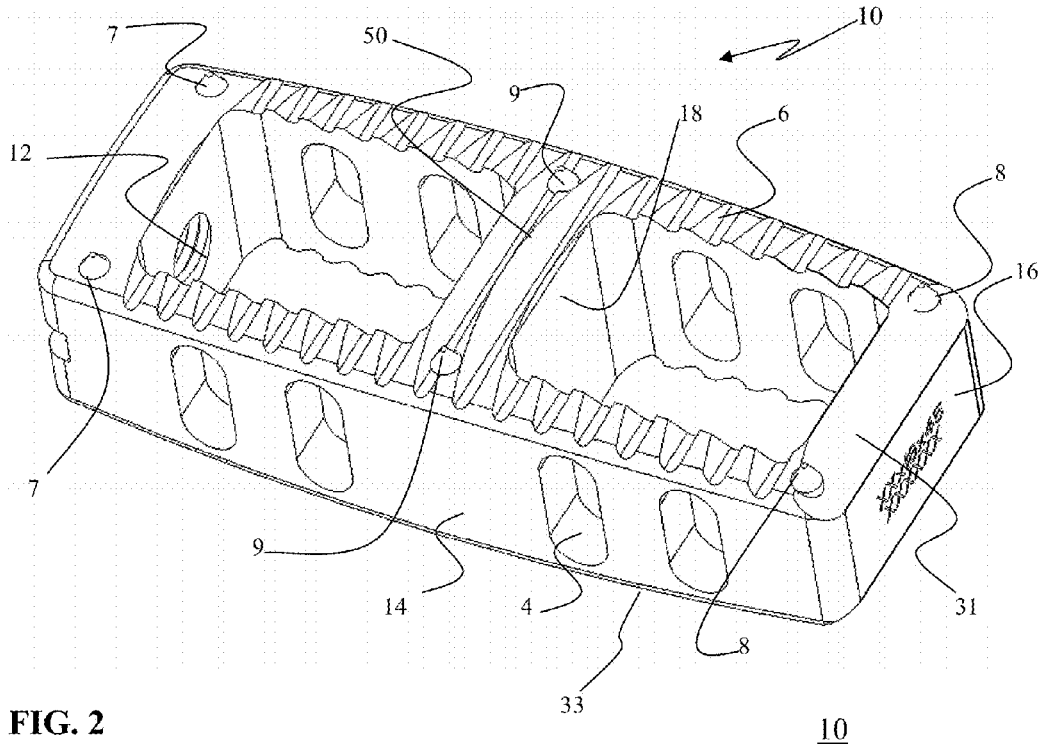


FIG. 2

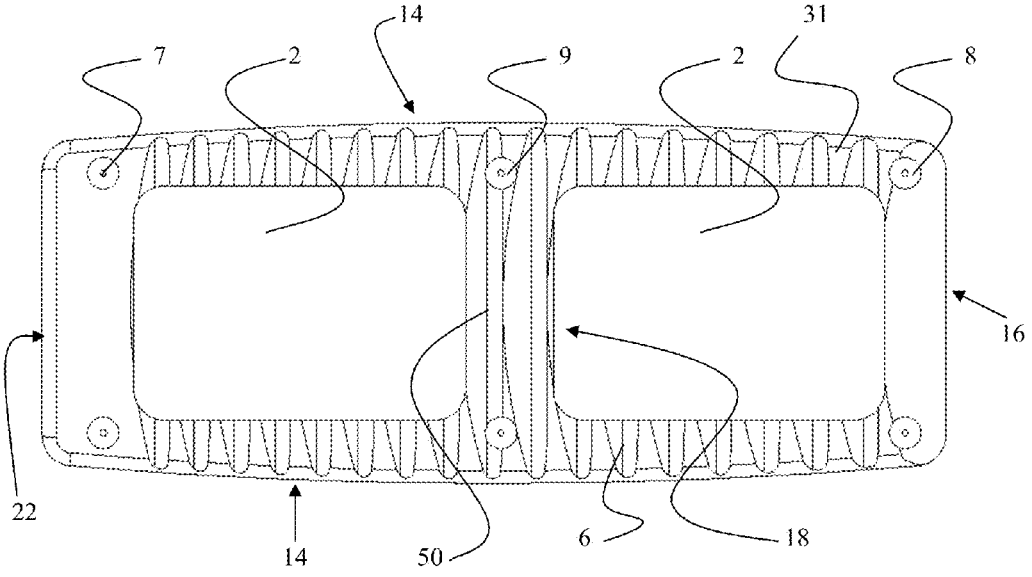


FIG. 3 10

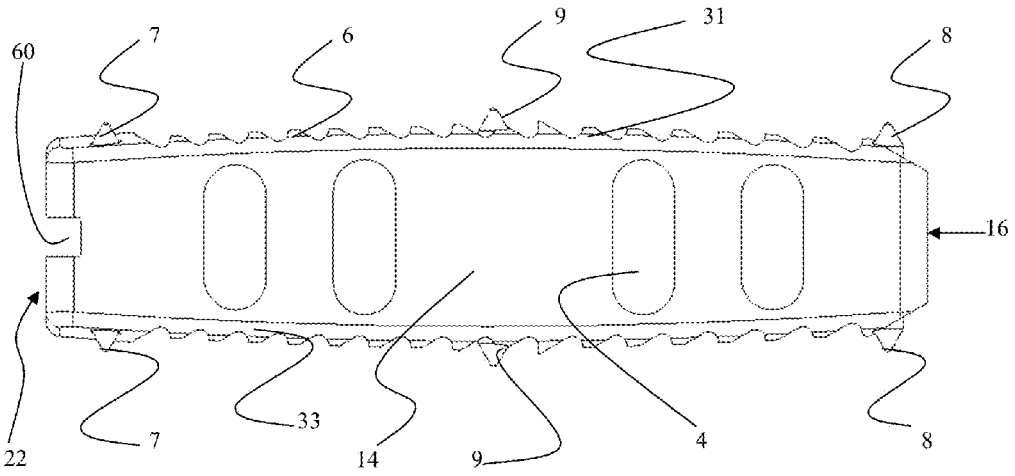


FIG. 4 10

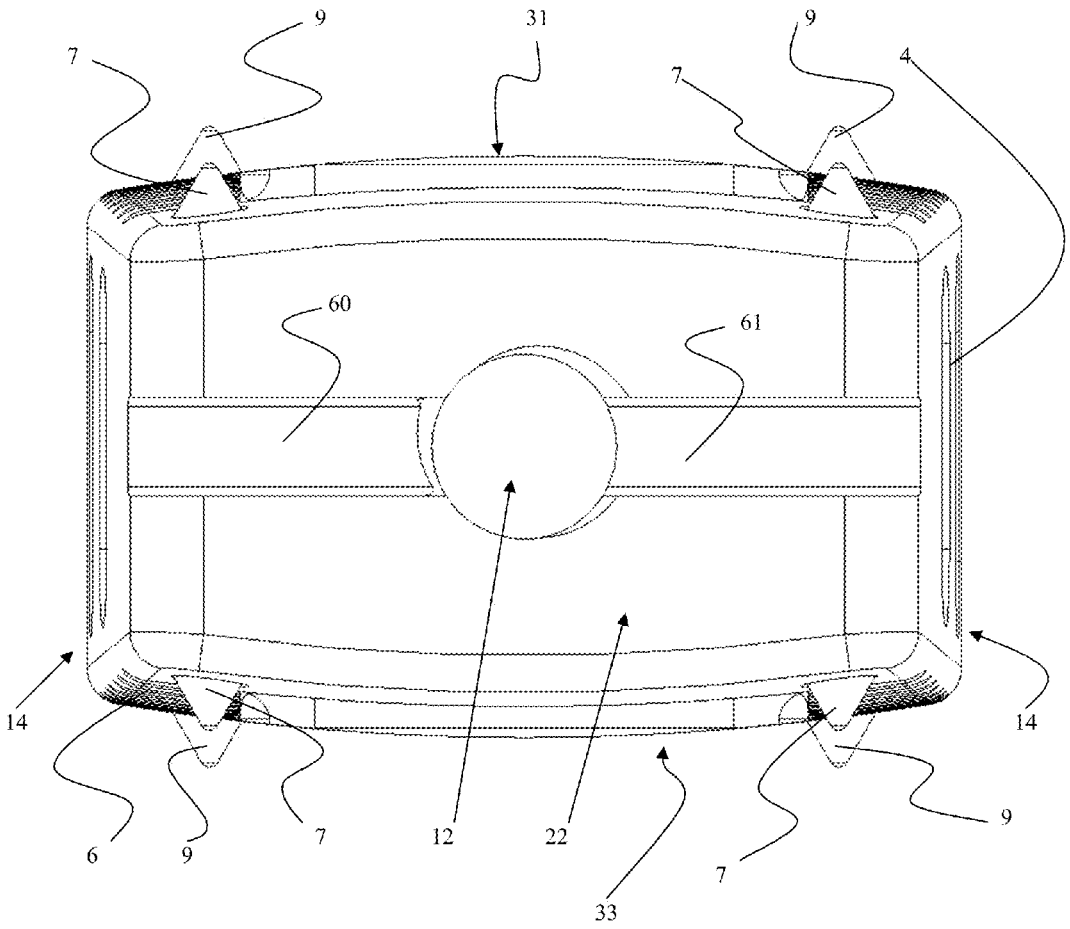


FIG. 5

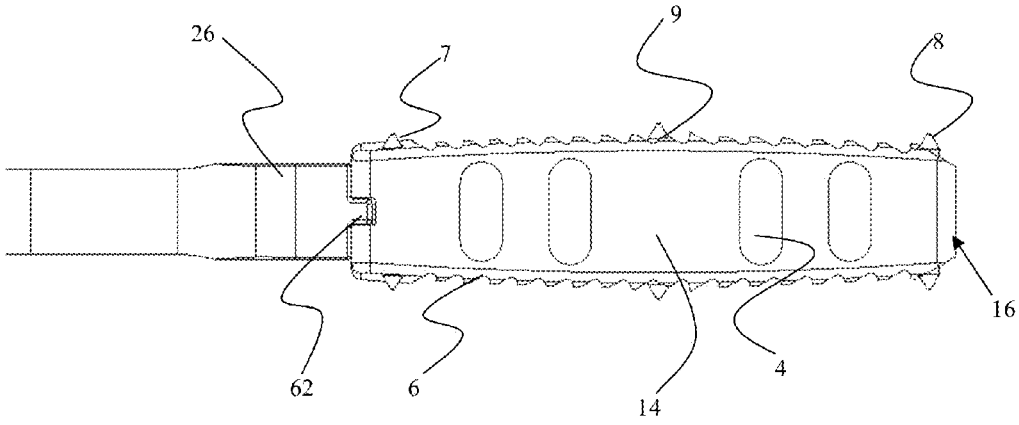


FIG. 6

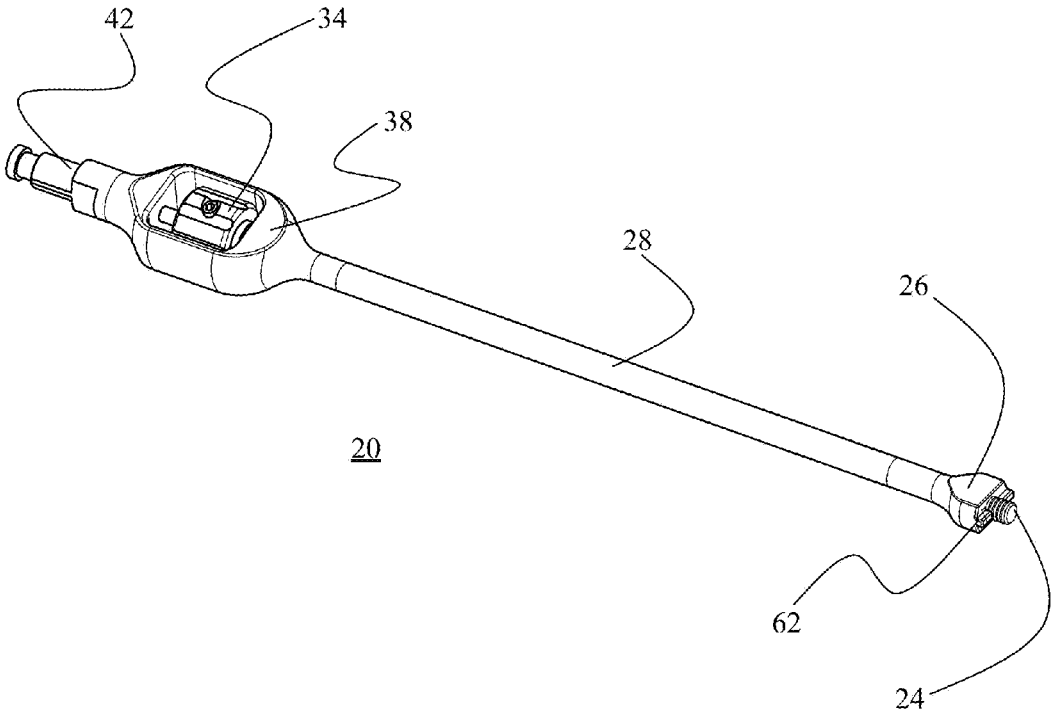


FIG. 7

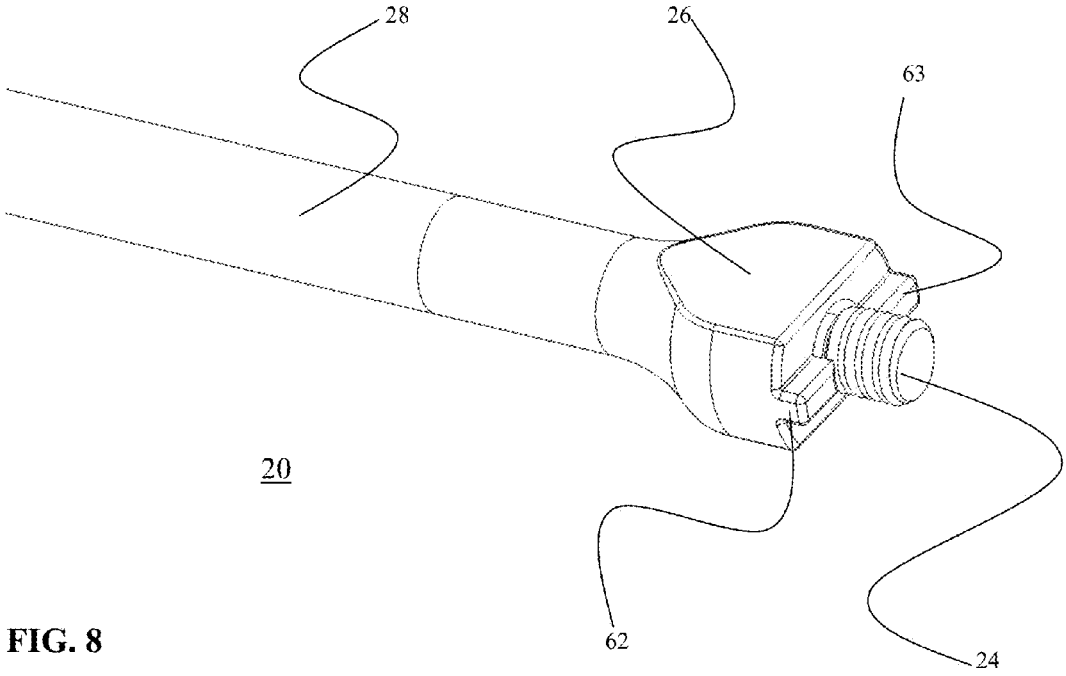


FIG. 8

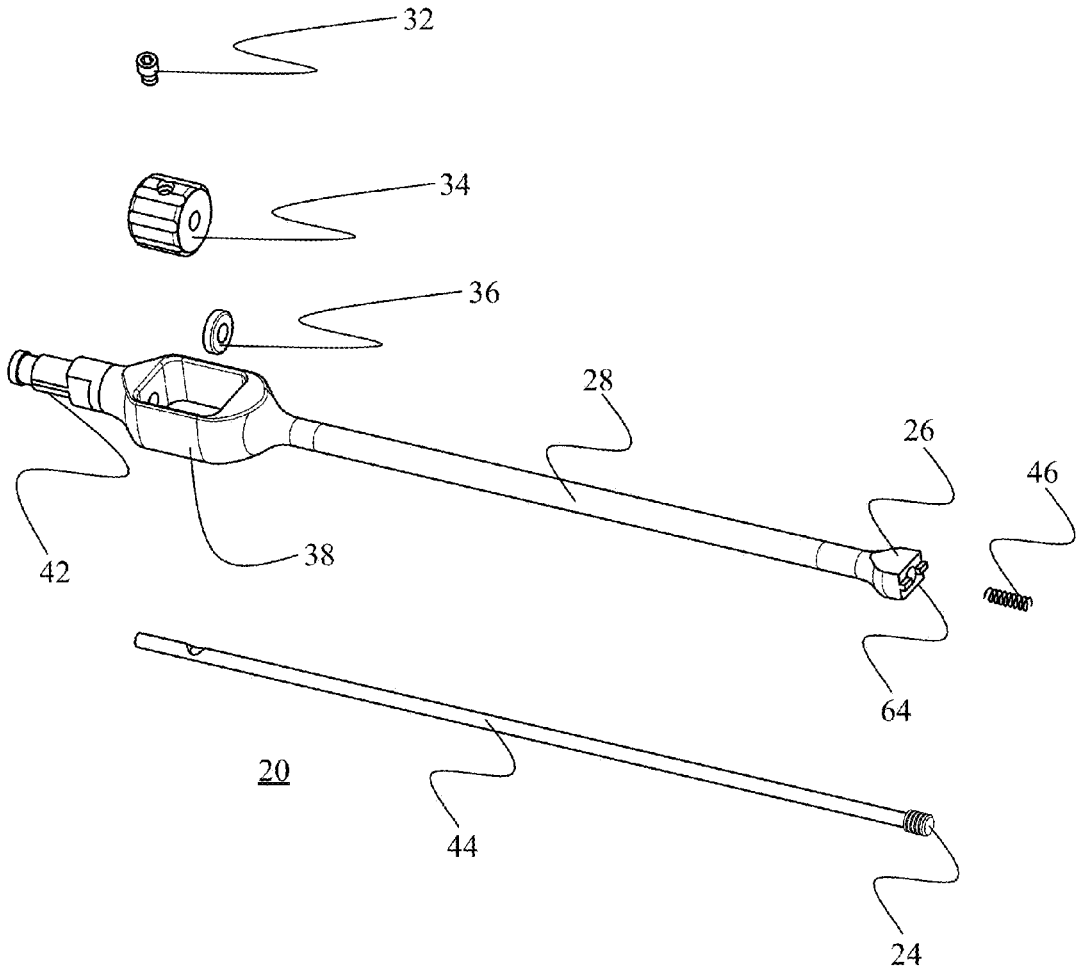


FIG. 9

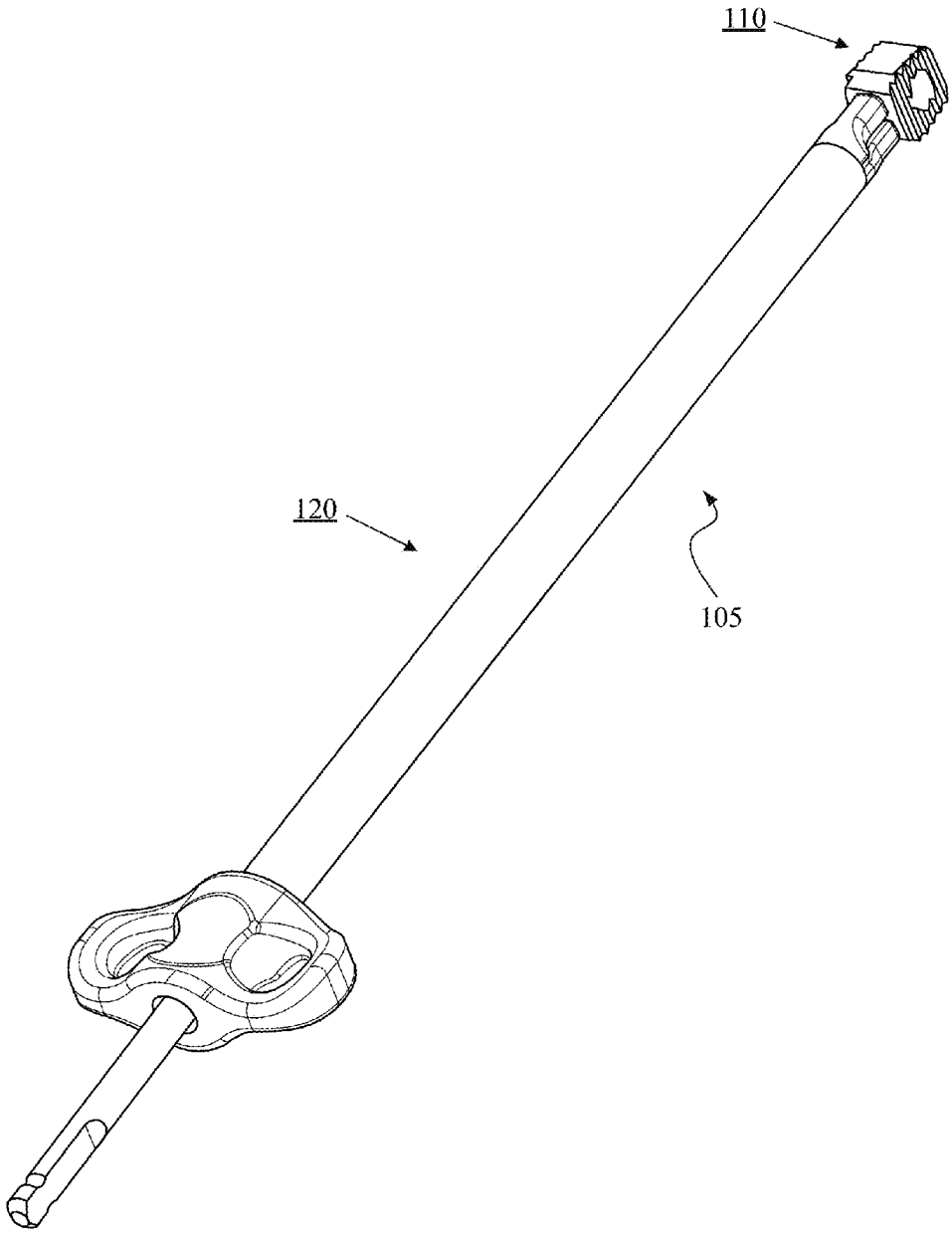


FIG. 10

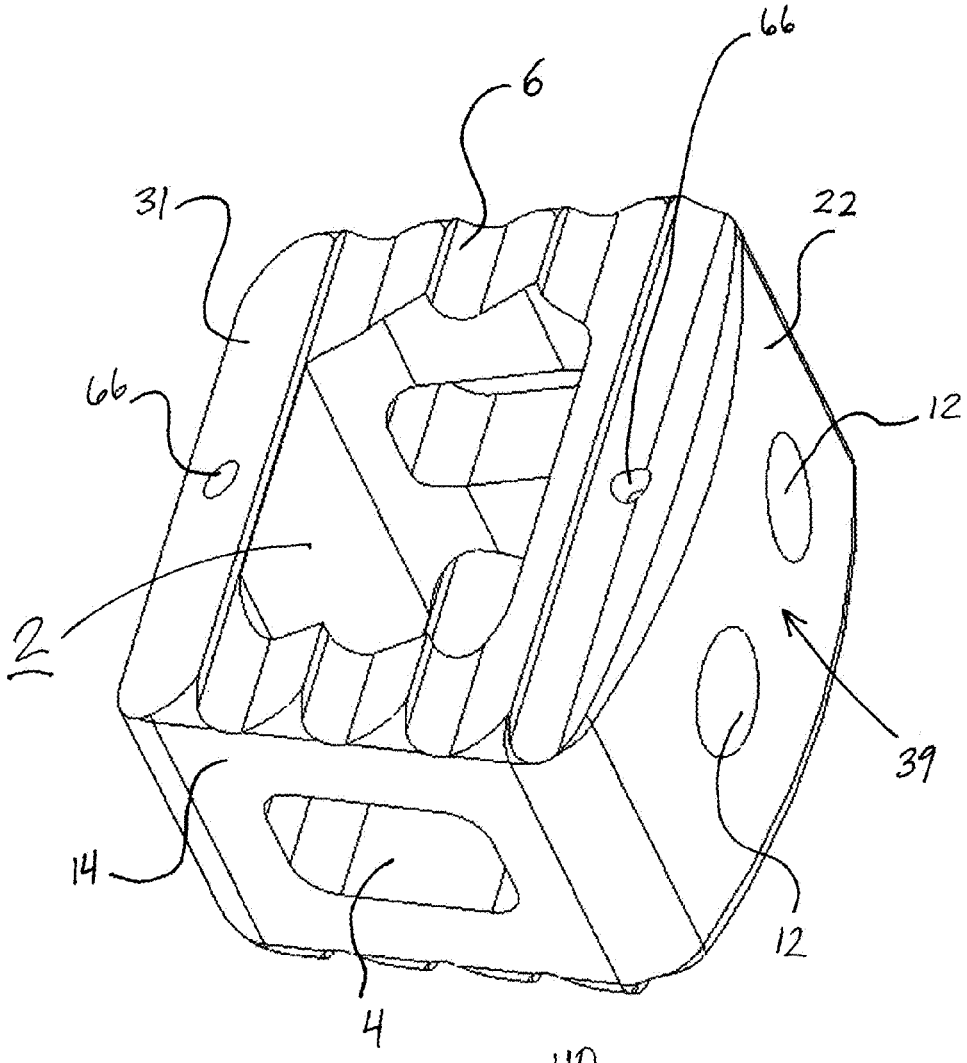


Fig. 11

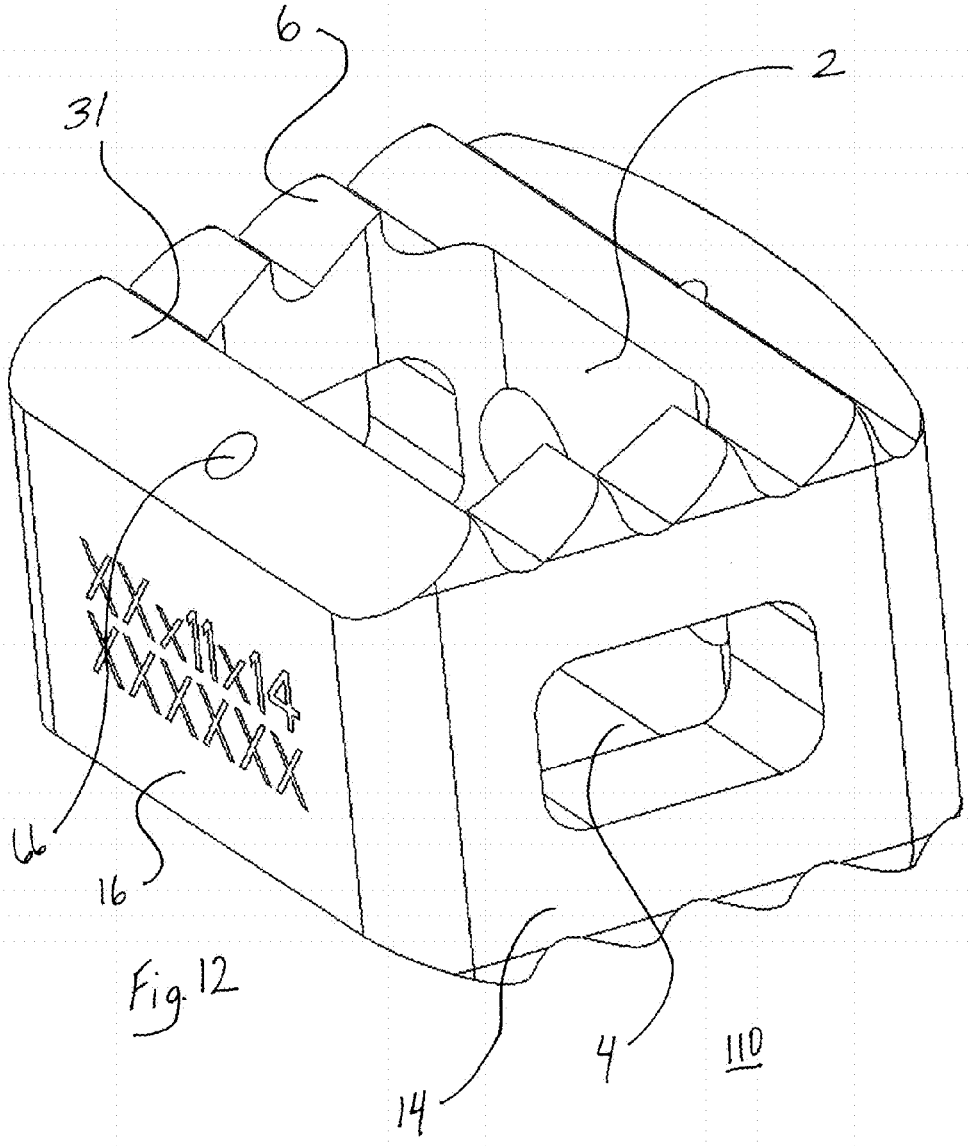


Fig. 12

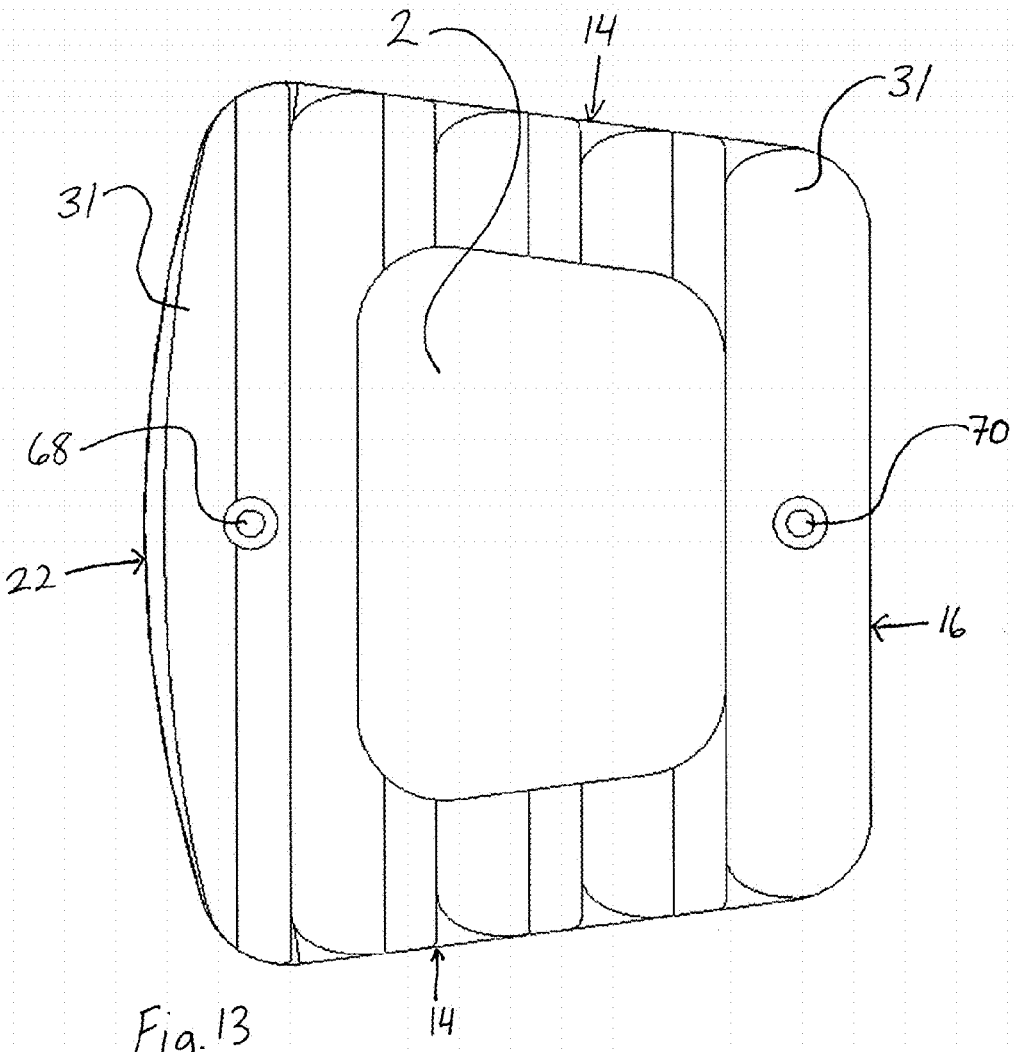


Fig. 13

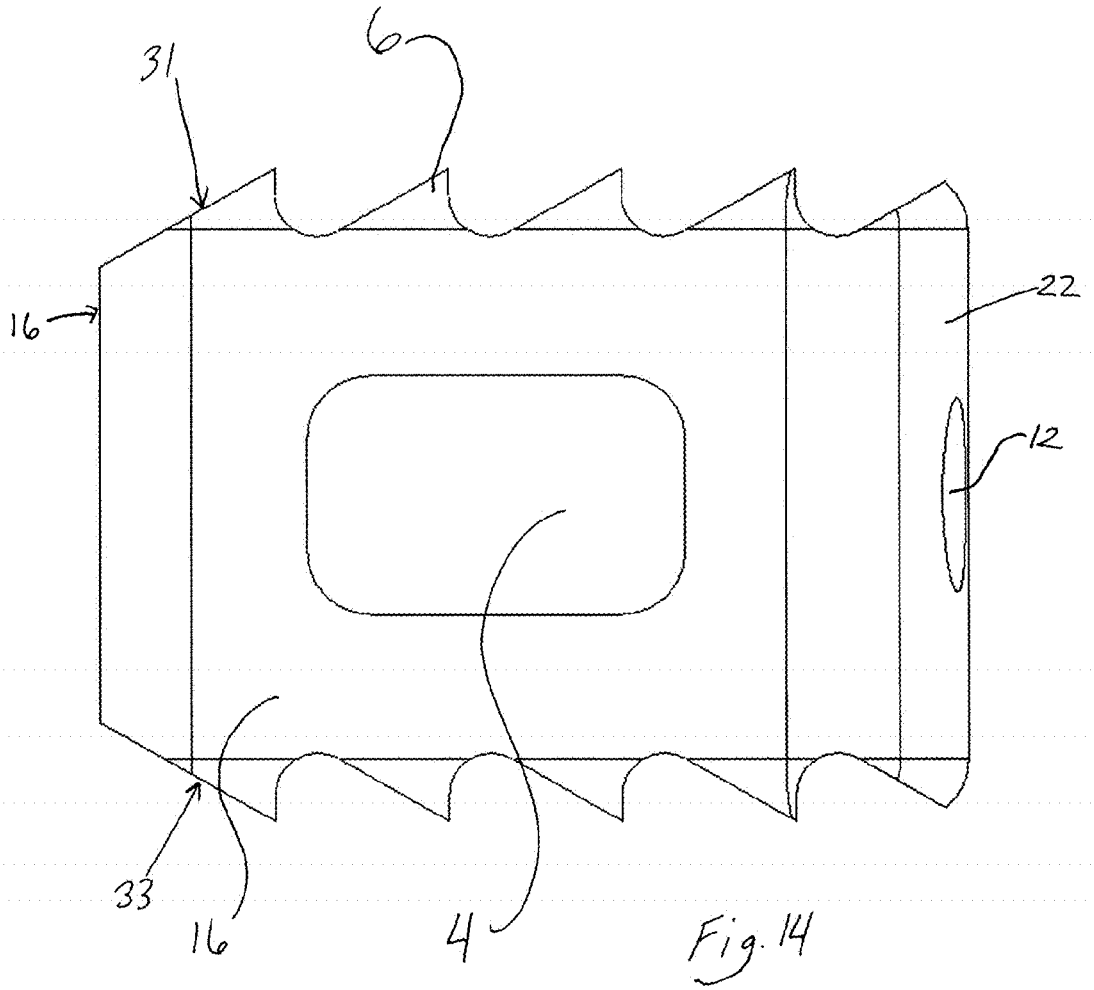


Fig. 14

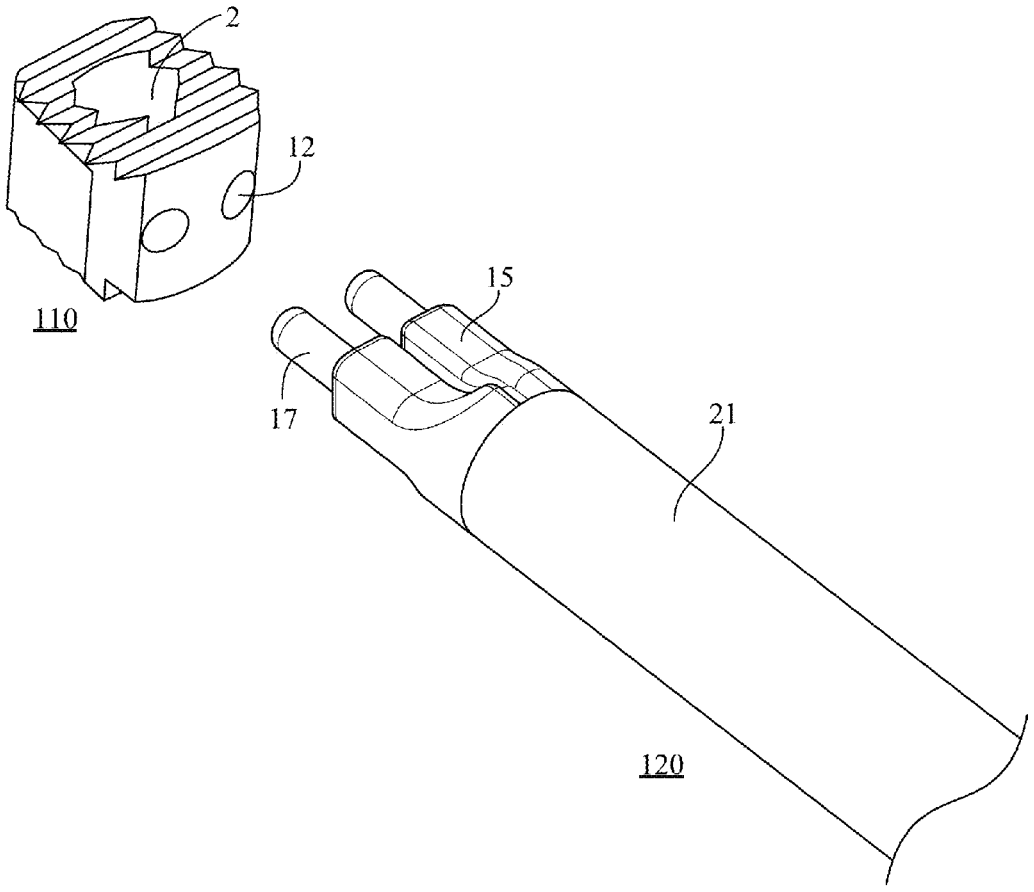


FIG. 15

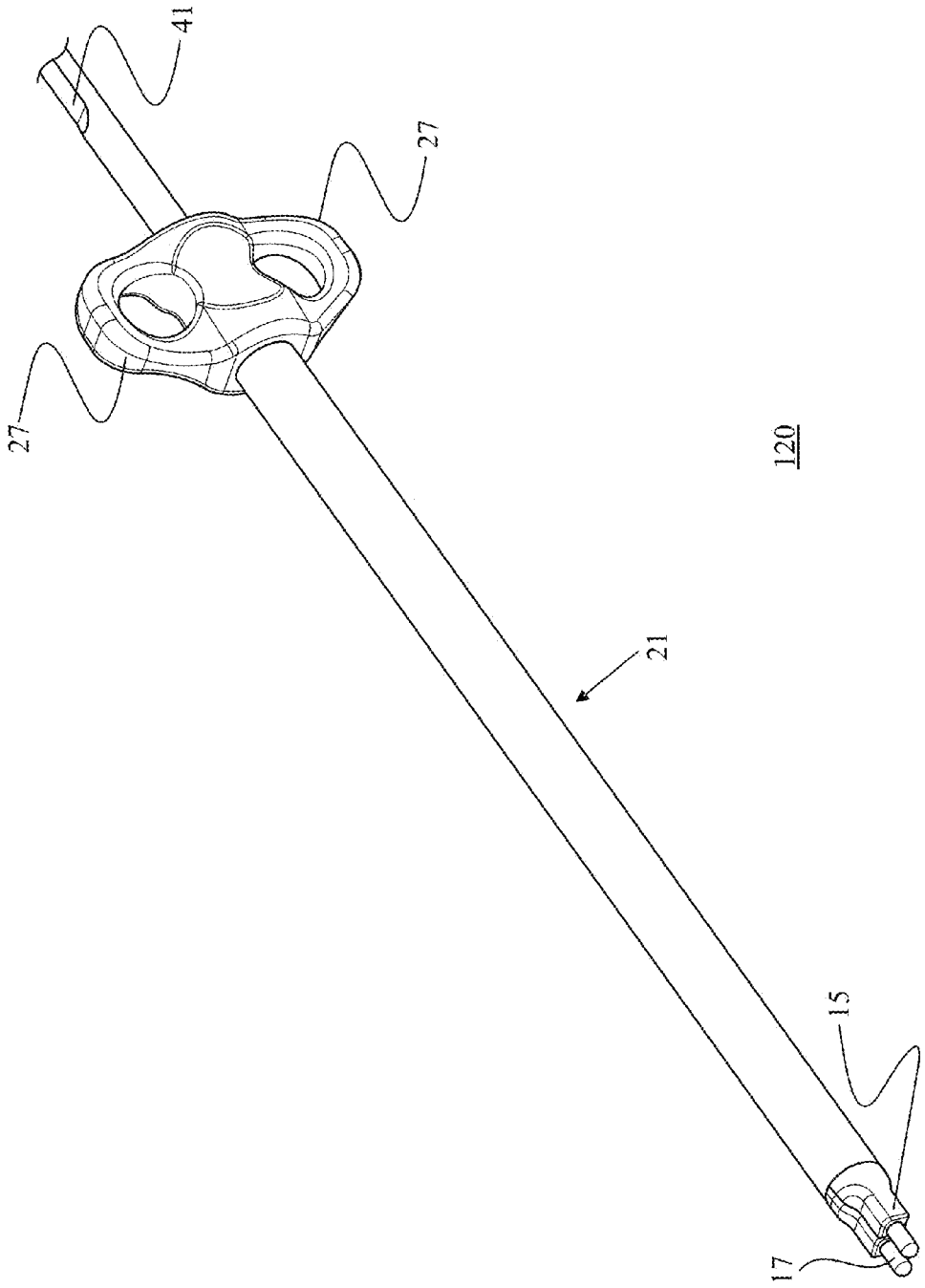


FIG. 16

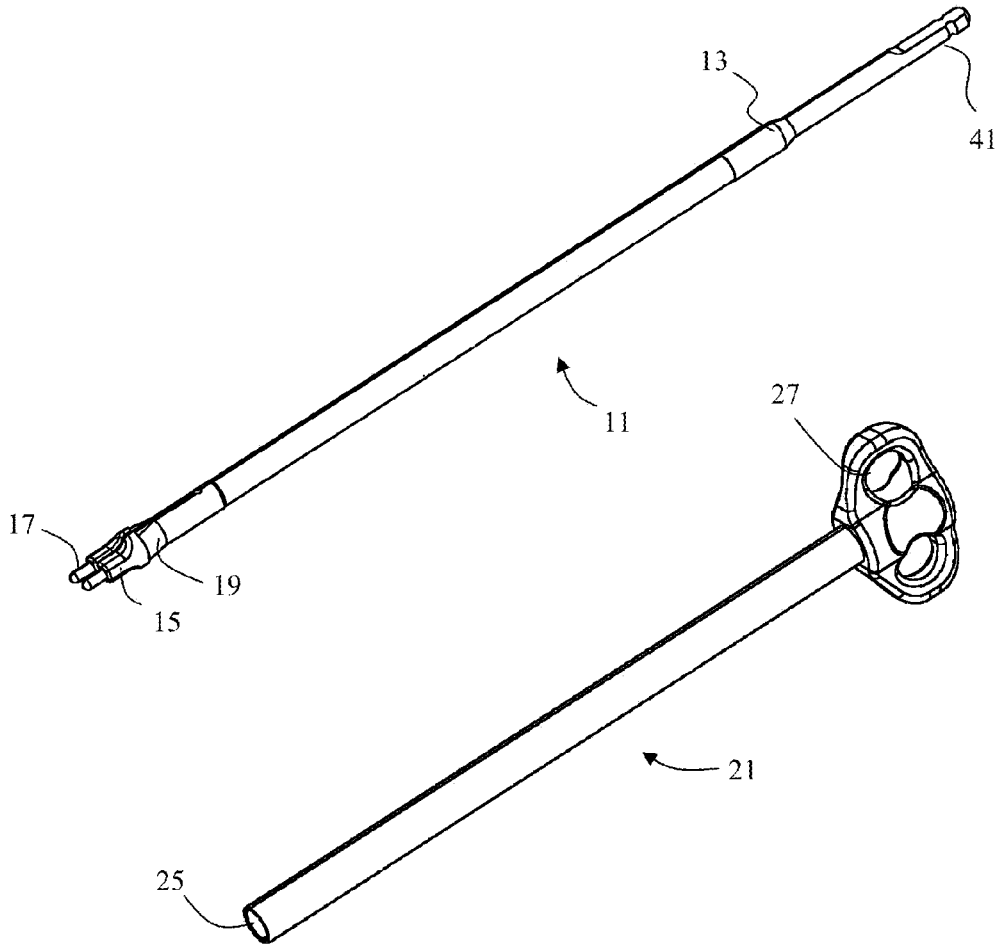


FIG. 17

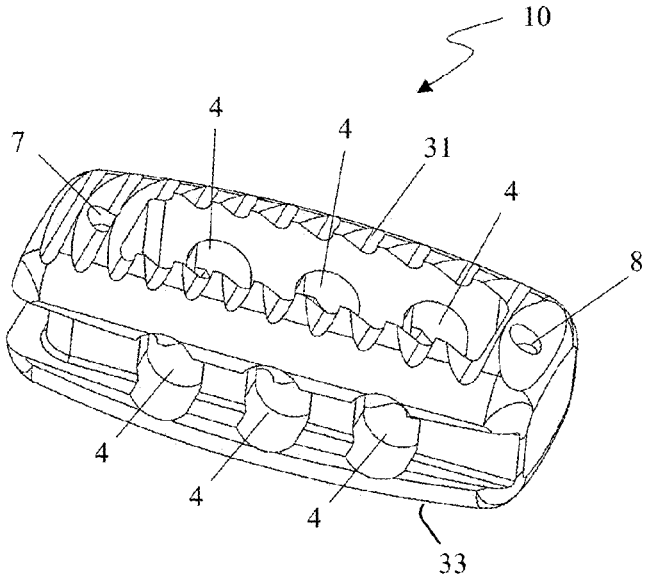


FIG. 18

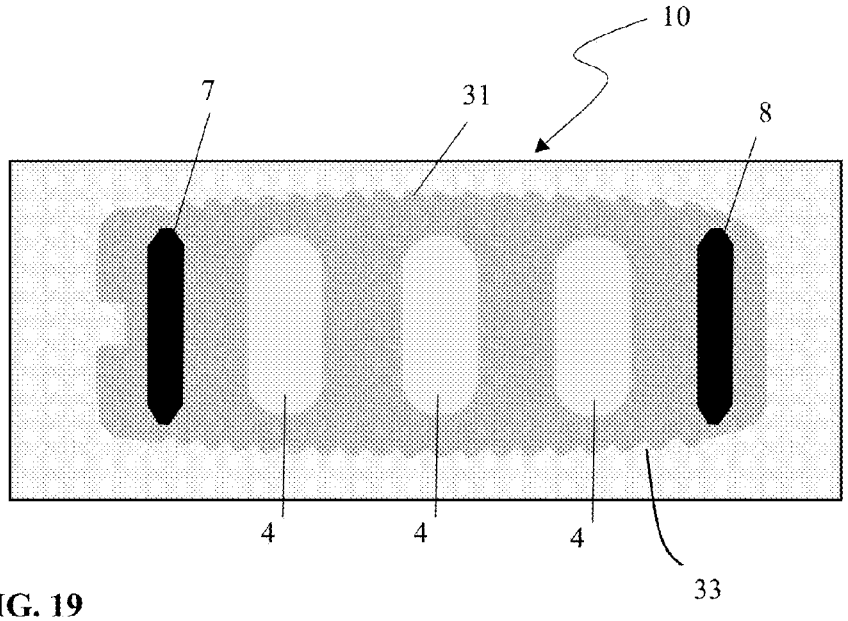
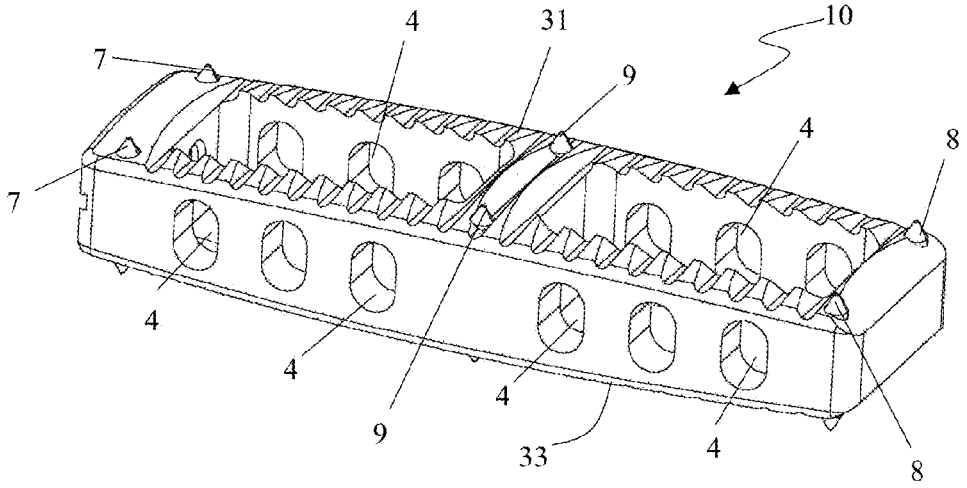


FIG. 19

FIG. 20



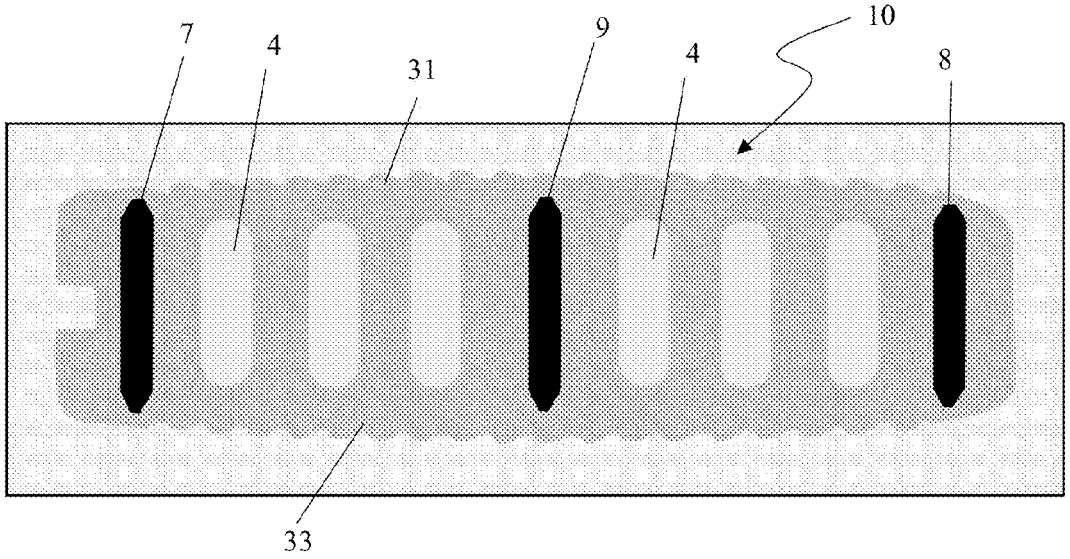


FIG. 21

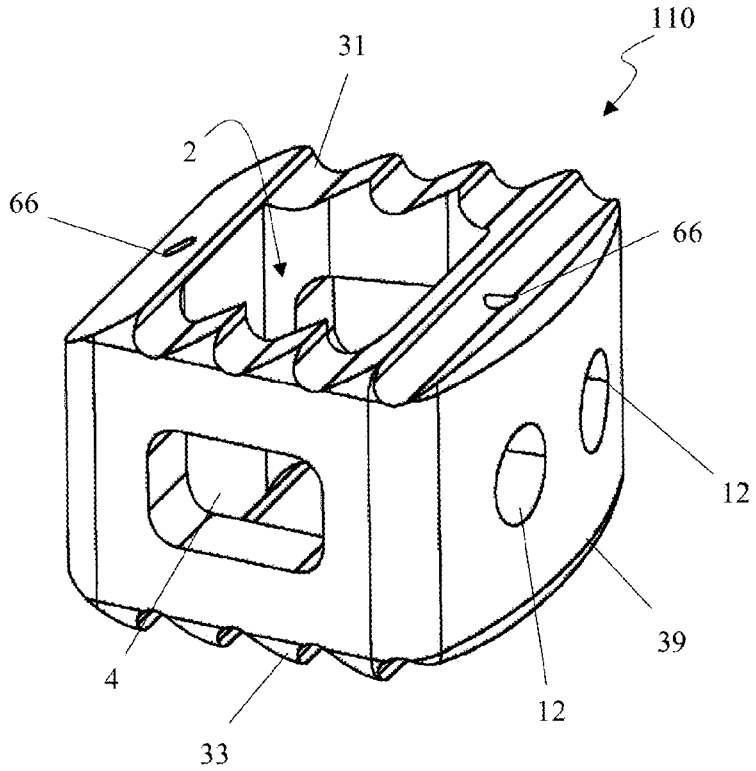


FIG. 22

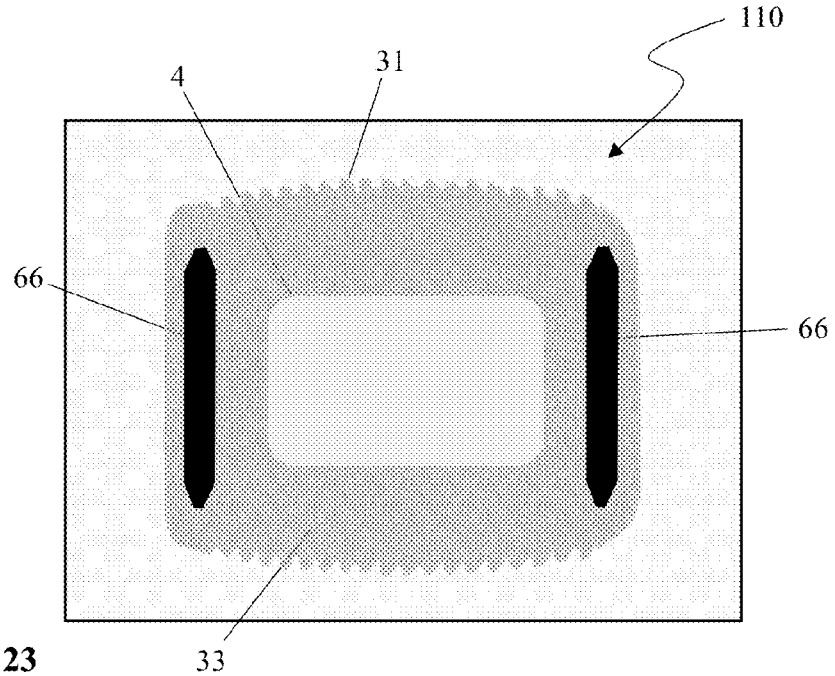


FIG. 23

SYSTEMS AND METHODS FOR SPINAL FUSION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 14/171,484 filed Feb. 3, 2014, which is a continuation of U.S. patent application Ser. No. 14/066,285 filed Oct. 29, 2013 (now U.S. Pat. No. 8,685,105), which is a continuation of U.S. patent application Ser. No. 13/748,925 filed Jan. 24, 2013 (now U.S. Pat. No. 8,574,301), which is a continuation of U.S. patent application Ser. No. 13/747,765 filed Jan. 23, 2013 (now U.S. Pat. No. 8,608,804), which is continuation of U.S. patent application Ser. No. 13/441,092 filed Apr. 6, 2012 (now U.S. Pat. No. 8,361,156), which is continuation of U.S. patent application Ser. No. 13/440,062 filed Apr. 5, 2012 (now U.S. Pat. No. 8,246,686), which is a continuation of U.S. patent application Ser. No. 13/079,645 filed Apr. 4, 2011 (now U.S. Pat. No. 8,187,334), which is continuation of U.S. patent application Ser. No. 11/093,409 filed Mar. 29, 2005 (now U.S. Pat. No. 7,918,891), which claims the benefit of the filing date under 35 USC 119(e) of United States Provisional Application entitled "Systems and Methods for Spinal Fusion," Ser. No. 60/557,536 filed Mar. 29, 2004, the entire contents of these prior applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates generally to spinal surgery and, more particularly, to a system and method for spinal fusion comprising a spinal fusion implant of non-bone construction releasably coupled to an insertion instrument dimensioned to introduce the spinal fusion implant into any of a variety of spinal target sites.

II. Discussion of the Prior Art

Currently there are nearly 500,000 spine lumbar and cervical fusion procedures performed each year in the United States. Such procedures are commonly performed to correct problems, such as chronic back or neck pain, which result from degenerated intervertebral discs or trauma. Generally, spinal fusion procedures involve removing some or all of the diseased or damaged disc, and inserting one or more intervertebral implants into the resulting disc space. Introducing the intervertebral implant serves to restore the height between adjacent vertebrae ("disc height"), which reduces if not eliminates neural impingement commonly associated with a damaged or diseased disc.

Autologous bone grafts are widely used intervertebral implant for lumbar fusion. Autologous bone grafts are obtained by harvesting a section of bone from the iliac crest of the patient and thereafter implanting the article of autologous bone graft to effect fusion. While generally effective, the use of autologous bone grafts suffers certain drawbacks. A primary drawback is the morbidity associated with harvesting the autologous graft from the patient's iliac crest. Another related drawback is the added surgical time required to perform the bone-harvesting.

Allograft bone grafts have been employed with increased regularity in an effort to overcome the drawbacks of autologous bone grafts. Allograft bone grafts are harvested from cadaveric specimens, machined, and sterilized for implantation. While allograft bone grafts eliminate the morbidity associated with iliac crest bone harvesting, as well as decrease the overall surgical time, they still suffer certain drawbacks. A primary drawback is supply constraint, in that the tissue banks that process and produce allograft bone implants find it difficult to forecast allograft given the inherent challenges in forecasting the receipt of cadavers. Another related drawback is that it is difficult to manufacture the allograft with consistent shape and strength characteristics given the variation from cadaver to cadaver.

The present invention is directed at overcoming, or at least improving upon, the disadvantages of the prior art.

SUMMARY OF THE INVENTION

The present invention overcomes the drawbacks of the prior art by providing a spinal fusion system and related methods involving the use of a spinal fusion implant of non-bone construction. The non-bone construction of the spinal fusion implant of the present invention overcomes the drawbacks of the prior art in that it is not supply limited (as with allograft) and does not require harvesting bone from the patient (as with autograft). The spinal fusion implant of the present invention may be comprised of any suitable non-bone composition, including but not limited to polymer compositions (e.g. poly-ether-ether-ketone (PEEK) and/or poly-ether-ketone-ketone (PEKK)), ceramic, metal or any combination of these materials.

The spinal fusion implant of the present invention may be provided in any number of suitable shapes and sizes depending upon the particular surgical procedure or need. The spinal fusion implant of the present invention may be dimensioned for use in the cervical and/or lumbar spine without departing from the scope of the present invention. For lumbar fusion, the spinal fusion implant of the present invention may be dimensioned, by way of example only, having a width ranging between 9 and 18 mm, a height ranging between 8 and 16 mm, and a length ranging between 25 and 45 mm. For cervical fusion, the spinal fusion implant of the present invention may be dimensioned, by way of example only, having a width about 11 mm, a height ranging between 5 and 12 mm, and a length about 14 mm.

The spinal fusion implant of the present invention may be provided with any number of additional features for promoting fusion, such as apertures extending between the upper and lower vertebral bodies which allow a boney bridge to form through the spinal fusion implant of the present invention. Such fusion-promoting apertures may be dimensioned to receive any number of suitable osteoinductive agents, including but not limited to bone morphogenic protein (BMP) and bio-resorbable polymers, including but not limited to any of a variety of poly (D,L-lactide-co-glycolide) based polymers. The spinal fusion implant of the present invention is preferably equipped with one or more lateral openings which aid it provides in visualization at the time of implantation and at subsequent clinical evaluations.

The spinal fusion implant of the present invention may be provided with any number of suitable anti-migration features to prevent spinal fusion implant from migrating or moving from the disc space after implantation. Suitable anti-migration features may include, but are not necessarily limited to, angled teeth formed along the upper and/or lower surfaces of the spinal fusion implant and/or spike elements disposed partially within and partially outside the upper and/or lower surfaces of the spinal fusion implant. Such anti-migration features provide the additional benefit of increasing the overall surface area between the spinal fusion implant of the present invention and the adjacent vertebrae, which promotes overall bone fusion rates.

The spinal fusion implant of the present invention may be provided with any number of features for enhancing the visualization of the implant during and/or after implantation into a spinal target site. According to one aspect of the present invention, such visualization enhancement features may take the form of the spike elements used for anti-migration, which may be manufactured from any of a variety of suitable materials, including but not limited to a metal, ceramic, and/or polymer material, preferably having radiopaque characteristics. The spike elements may also take any of a variety of suitable shapes, including but not limited to a generally elongated element disposed within the implant such that the ends thereof extend generally perpendicularly from the upper and/or lower surfaces of the implant. The spike elements may each comprise a unitary element extending through upper and lower surfaces or, alternatively, each spike element may comprise a shorter element which only extends through a single surface (that is, does not extend through the entire height of the implant). In any event, when the spike elements are provided having radiodense characteristics and the implant is manufactured from a radiolucent material (such as, by way of example only, PEEK and/or PEKK), the spike elements will be readily observable under X-ray or fluoroscopy such that a surgeon may track the progress of the implant during implantation and/or the placement of the implant after implantation.

The spinal implant of the present invention may be introduced into a spinal target site through the use of any of a variety of suitable instruments having the capability to releasably engage the spinal implant. In a preferred embodiment, the insertion instrument permits quick, direct, accurate placement of the spinal implant of the present invention into the intervertebral space. According to one embodiment, the insertion instrument includes a threaded engagement element dimensioned to threadably engage into a receiving aperture formed in the spinal fusion implant of the present invention. According to another embodiment, the insertion instrument includes an elongate fork member and a generally tubular lock member.

BRIEF DESCRIPTION OF THE DRAWINGS

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

FIG. **1** is a perspective view of a spinal fusion system of the present invention, including a lumbar fusion implant releasably coupled to an insertion instrument according to one embodiment of the present invention;

FIG. **2** is a perspective view of the lumbar fusion implant of FIG. **1**, illustrating (among other things) fusion apertures extending between top and bottom surfaces, a plurality of visualization apertures extending through the side walls, and a variety of anti-migration features according to one embodiment of the present invention;

FIG. **3** is a top view of the lumbar fusion implant of FIG. **1**, illustrating (among other things) the fusion apertures and the anti-migration features according to one embodiment of the present invention;

FIG. **4** is a side view of the lumbar fusion implant of FIG. **1**, illustrating (among other things) the visualization apertures, the anti-migration feature, and a receiving aperture for releasably engaging the insertion instrument of FIG. **1** according to one embodiment of the present invention;

FIG. **5** is an end view of the lumbar fusion implant of FIG. **1**, illustrating (among other things) the receiving aperture formed in the proximal end, the anti-migration features, and the visualization apertures according to one embodiment of the present invention;

FIG. **6** is an enlarged side view of the lumbar fusion implant of FIG. **1** releasably coupled to the distal end of the insertion instrument of FIG. **1** according to one embodiment of the present invention;

FIG. **7** is a perspective view of the insertion instrument of FIG. **1** in a fully assembled form according to one embodiment of the present invention;

FIG. **8** is an enlarged perspective view of the distal region of the insertion instrument of FIG. **1** according to one embodiment of the present invention;

FIG. **9** is a perspective exploded view of the insertion instrument of FIG. **1**, illustrating the component parts of the insertion instrument according to one embodiment of the present invention;

FIG. **10** is a perspective view of a spinal fusion system of the present invention, including a cervical fusion implant releasably coupled to a cervical insertion instrument according to one embodiment of the present invention;

FIG. **11** is a perspective view of the proximal side of the cervical fusion implant of FIG. **10**, illustrating (among other things) fusion apertures extending between top and bottom surfaces, a plurality of visualization apertures extending through the lateral walls, a plurality of receiving apertures, and a variety of anti-migration features according to one embodiment of the present invention;

FIG. **12** is a perspective view of the distal side cervical fusion implant of FIG. **10**, illustrating (among other things) the visualization apertures and anti-migration features;

FIG. **13** is a top view of the cervical fusion implant of FIG. **10**, illustrating (among other things) the fusion apertures and anti-migration features according to one embodiment of the present invention;

FIG. **14** is a side view of the cervical fusion implant of FIG. **10**, illustrating (among other things) the visualization apertures, the anti-migration features, and one of two receiving apertures provided in the proximal end for releasably engaging the cervical insertion instrument of FIG. **10** according to one embodiment of the present invention;

FIG. **15** is a perspective view of the cervical fusion implant of the present invention just prior to attachment to the cervical insertion device according to one embodiment of the present invention;

FIG. **16** is a perspective view of the insertion instrument of FIG. **10** in a fully assembled form according to one embodiment of the present invention;

FIG. **17** is a perspective exploded view of the insertion instrument of FIG. **10**, illustrating the component parts of the insertion instrument according to one embodiment of the present invention;

FIGS. **18** and **19** are perspective and side views, respectively, illustrating the "enhanced visualization" feature of the present invention as employed within a lumbar fusion implant according to one embodiment of the present invention;

FIGS. **20** and **21** are perspective and side views, respectively, illustrating the "enhanced visualization" feature of the present invention as employed within a lumbar fusion implant according to one embodiment of the present invention; and

FIGS. **22** and **23** are perspective and side views, respectively, illustrating the "enhanced visualization" feature of the present invention as employed within a cervical fusion implant according to one embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. The system to facilitate bone fusion and related methods disclosed herein boasts a variety of inventive features and components that warrant patent protection, both individually and in combination.

FIG. **1** illustrates, by way of example only, a spinal fusion system **5** for performing spinal fusion between adjacent lumbar vertebrae, including an exemplary spinal fusion implant **10** and an exemplary insertion instrument **20** provided in accordance with the present invention. The spinal fusion implant **10** may be comprised of any suitable non-bone composition having suitable radiolucent characteristics, including but not limited to polymer compositions (e.g. poly-ether-ether-ketone (PEEK) and/or poly-ether-ketone-ketone (PEKK)) or any combination of PEEK and PEKK. The spinal fusion implant **10** of the present invention may be dimensioned, by way of example only, having a width ranging between 9 and 18 mm, a height ranging between 8 and 16 mm, and a length ranging between 25 and 45 mm.

As will be described in detail below, the insertion instrument **20** is configured to releasably maintain the exemplary spinal fusion implant **10** in the proper orientation during insertion into a lumbar disc space and thereafter release to deposit the implant **10**. The exemplary spinal fusion implant **10**, having been deposited in the disc space, facilitates spinal fusion over time by maintaining a restored disc height as natural bone growth occurs through and/or past the implant **10**, resulting in the formation of a boney bridge extending between the adjacent vertebral bodies. The implant **10** is particularly suited for introduction into the disc space via a lateral (trans-psoas) approach to the spine, but may be introduced in any of a variety of approaches, such as posterior, anterior, antero-lateral, and postero-lateral, without departing from the scope of the present invention (depending upon the sizing of the implant **10**).

The spinal fusion implant **10** of the present invention may be provided with any number of additional features for promoting fusion, such as apertures **2** extending between the upper and lower vertebral bodies which allow a boney bridge to form through the spinal fusion implant **10**. According to a still further aspect of the present invention, this fusion may be facilitated or augmented by introducing or positioning various osteoinductive materials within the apertures **2** and/or adjacent to the spinal fusion implant **10**. Such osteoinductive materials may be introduced before, during, or after the insertion of the exemplary spinal fusion implant **10**, and may include (but are not necessarily limited to) autologous bone harvested from the patient receiving the spinal fusion implant **10**, bone allograft, bone xenograft, any number of non-bone implants (e.g. ceramic, metallic, polymer), bone morphogenic protein, and bio-resorbable compositions, including but not limited to any of a variety of poly (D,L-lactide-co-glycolide) based polymers.

The spinal fusion implant **10** of the present invention is preferably equipped with one or more visualization apertures **4** situated along the lateral sides, which aid in visualization at the time of implantation and at subsequent clinical evaluations. More specifically, based on the generally radiolucent nature of the implant **10**, the visualization apertures **4** provide the ability to visualize the interior of the implant **10** during X-ray and/or other suitable imaging techniques which are undertaken from the side (or "lateral") perspective of the implant **10**. If fusion has taken place, the visualization apertures **4** will provide a method for the surgeon to make follow up assessments as to the degree of fusion without any visual interference from the spinal fusion implant **10**. Further, the visualization apertures **4** will provide an avenue for cellular migration to the exterior of the spinal fusion implant **10**. Thus the spinal fusion implant **10** will serve as additional scaffolding for bone fusion on the exterior of the spinal fusion implant **10**.

FIGS. **2-5** depict various embodiments of the exemplary spinal fusion implant **10**. Some common attributes are shared among the various embodiments. More specifically, each spinal fusion implant **10** has a top surface **31**, a bottom surface **33**, lateral sides **14**, a proximal side **22**, and a distal side **16**. In one embodiment, the top and bottom surfaces **31**, **33** are generally parallel. It can be appreciated by one skilled in the art that although the surfaces **31**, **33** are generally parallel to one another, they may be provided in any number of suitable shapes, including but not limited to concave and/or convex. When provided as convex shapes, the top and bottom surfaces **31**, **33** may better match the natural contours of the vertebral end plates. Although not shown, it will be appreciated that the top and bottom surfaces **31**, **33** may be angled relative to one another to better match the natural lordosis of the lumbar and cervical spine or the natural kyphosis of the thoracic spine.

The exemplary spinal fusion implant **10** also preferably includes anti-migration features designed to increase the friction between the spinal fusion implant **10** and the adjacent contacting surfaces of the vertebral bodies so as to prohibit migration of the spinal fusion implant **10** after implantation. Such anti-migration features may include ridges **6** provided along the top surface **31** and/or bottom surface **33**. Additional anti-migration features may also include a pair of spike elements **7** disposed within the proximal region of the implant **10**, a pair of spike elements **8** disposed within the distal region of the implant **10**, and a pair of spike elements **9** disposed within the central region of the implant **10**. Spike elements **7**, **8**, **9** may extend from the top surface **31** and/or bottom surface **33** within the respective proximal, distal and central regions of the implant **10**. The spike elements **7**, **8**, **9** may be manufactured from any of a variety of suitable materials, including but not limited to a metal, ceramic, and/or polymer material, preferably having radiopaque characteristics. The spike elements **7**, **8**, **9** may also take any of a variety of suitable shapes, including but not limited to a generally elongated element disposed within the implant **10** such that the ends thereof extend generally perpendicularly from the upper and/or lower surfaces **31**, **33** of the implant **10**. As best appreciated in FIG. **4**, the spike elements **7**, **8**, **9** may each comprise a unitary element extending through upper and lower surfaces **31**, **33**. Alternatively, each spike element **7**, **8**, **9** may comprise a shorter element which only extends through a single surface **31**, **33** (that is, does not extend through the entire height of the implant **10**). In any event, when the spike elements **7**, **8**, **9** are provided having radiodense characteristics and the implant **10** is manufactured from a radiolucent material (such as, by way of example only, PEEK and/or PEKK), the spike elements **7**, **8**, **9** will be readily observable under X-ray or fluo-

roscopy such that a surgeon may track the progress of the implant **10** during implantation and/or the placement of the implant **10** after implantation.

The spinal fusion implant **10** has two large fusion apertures **2**, separated by a medial support **50**, extending in a vertical fashion through the top surface **31** and bottom surface **33**. The fusion apertures **2** function primarily as an avenue for bony fusion between adjacent vertebrae. The fusion apertures **2** may be provided in any of a variety of suitable shapes, including but not limited to the generally rectangular shape best viewed in FIG. **3**, or a generally circular, oblong and/or triangular shape or any combination thereof. The spinal fusion implant **10** may have a plurality of visualization apertures **4** which allow a clinician to make visual observations of the degree of bony fusion un-obscured by the lateral side **14** to facilitate further diagnosis and treatment. The visualization apertures **4** may be provided in any of a variety of suitable shapes, including but not limited to the generally oblong shape best viewed in FIG. **4**, or a generally circular, rectangular and/or triangular shape or any combination thereof.

The spinal fusion implant **10** may be provided with any number of suitable features for engaging the insertion instrument **20** without departing from the scope of the present invention. As best viewed in FIGS. **4-6**, one engagement mechanism involves providing a threaded receiving aperture **12** in the proximal sidewall **22** of the spinal fusion implant **10** of the present invention. The threaded receiving aperture **12** is dimensioned to threadably receive a threaded connector **24** on the insertion instrument **20** (as will be described in greater detail below). The receiving aperture **12** extends inwardly from the proximal side **22** in a generally perpendicular fashion relative to the proximal side **22**. Although shown as having a generally circular cross-section, it will be appreciated that the receiving aperture **12** may be provided having any number of suitable shapes or cross-sections, including but not limited to rectangular or triangular. In addition to the receiving aperture **12**, the spinal fusion implant **10** is preferably equipped with a pair of grooved purchase regions **60**, **61** extending generally horizontally from either side of the receiving aperture **12**. The grooved purchase regions **60**, **61** are dimensioned to receive corresponding distal head ridges **62**, **63** on the insertion instrument **20** (as will be described in greater detail below), which collectively provide an enhanced engagement between the implant **10** and instrument **20**.

FIGS. **6-9** detail the exemplary insertion instrument **20** according to one embodiment of the invention. The exemplary insertion instrument **20** includes an elongate tubular element **28** and an inserter shaft **44**. The elongate tubular element **28** is constructed with a distal head **26** at its distal end, distal head ridges **62**, **63** on the distal end of the distal head **26**, a thumbwheel housing **38** at its proximal end and a handle **42** at its proximal end. The elongate tubular element **28** is generally cylindrical and of a length sufficient to allow the device to span from the surgical target site to a location sufficiently outside the patient's body so the handle **42** and thumbwheel housing **38** can be easily accessed by a clinician or a complimentary controlling device.

The elongate tubular element **28** is dimensioned to receive a spring **46** and the proximal end of the inserter shaft **44** into the inner bore **64** of the elongate tubular element **28**. The inserter shaft **44** is dimensioned such that the threaded connector **24** at the distal end of the inserter shaft **44** just protrudes past the distal head ridges **62**, **63** to allow engagement with the receiving aperture **12** of the spinal fusion implant **10**. It should be appreciated by one skilled in the art that such a construction allows the inserter shaft **44** to be able to rotate freely within the elongate tubular element **28** while stabilized by a spring **46** to reduce any slidable play in the insertion instrument **20**.

The handle **42** is generally disposed at the proximal end of the insertion instrument **20**. The handle **42** is fixed to the thumbwheel housing **38** allowing easy handling by the clinician. Because the handle **42** is fixed the clinician has easy access to the thumbwheel **34** and can stably turn the thumbwheel **34** relative to the thumbwheel housing **38**. Additionally, the relative orientation of the thumbwheel housing **38** to the handle **42** orients the clinician with respect to the distal head **26** and distal head ridge **62**. By way of example, the thumbwheel housing **38** holds a thumbwheel **34**, a set screw **32**, and a spacer **36**. The inserter shaft **44** is attached to the thumbwheel **34** and is freely rotatable with low friction due to the spacer **36**. One skilled in the art can appreciate myriad methods of assembling a housing similar to the above described.

FIG. **6** details the distal head ridge of the exemplary insertion instrument **20** coupled to the spinal fusion implant **10** through the purchase regions **60**, **61**. The distal head ridges **62**, **63** are dimensioned to fit slidably into the purchase regions **60**, **61** with low friction to allow accurate engagement of the threaded connector **24** to the receiving aperture **12** of the spinal fusion implant **10**. In the presented embodiment, the outer dimension of the threaded connector **24** is smaller than the largest outer dimension of the distal head **26** and elongate tubular element **28**. Alternatively, other methods of creating a gripping surface are contemplated including but not limited to knurling or facets.

In order to use the system to perform a spinal fusion procedure, the clinician must first designate the appropriate implant size. After the spinal fusion implant **10** is chosen, the distal head ridges **62**, **63** of the inserter shaft **44** are inserted into the purchase regions **60**, **61** of the spinal fusion implant **10**. At that time the spinal fusion implant **10** and insertion instrument **20** are slidably engaged with one another. Before the clinician can manipulate the combined spinal fusion implant **10** and insertion instrument **20**, they must be releasably secured together. In order to secure the spinal fusion implant **10** onto the threaded connector **24** of the inserter instrument **20**, the clinician employs the thumbwheel **34** to rotate the inserter shaft **44** and threaded connector **24**. The rotation of the threaded connector **24** will releasably engage the receiving aperture of the spinal fusion implant **10** and stabilize the insertion instrument **20** relative to the spinal fusion implant **10**.

A clinician can utilize the secured system in either an open or minimally invasive spinal fusion procedure. In either type of procedure, a working channel is created in a patient that reaches the targeted spinal level. After the creation of that channel, the intervertebral space may be prepared via any number of well known preparation tools, including but not limited to kerrisons, rongeurs, pituitaries, and rasps. After preparation, the insertion instrument **20** is used to place a spinal fusion implant **10** into the prepared intervertebral space. Once the implant **10** is inserted into the prepared space, the implant **10** is released from the insertion instrument **20** by rotating the thumbwheel **34** to disengage the threaded connector **24** from the receiving aperture **12**. That motion removes the compressive force on the purchase regions **60**, **61** between the distal head **26** and the distal head ridges **62**, **63** of the spinal fusion implant **10** and allows the insertion instrument to be slidably removed from the implant **10**. After the threaded connector **24** is disengaged from the implant **10**, the insertion instrument **20** is removed from the working channel and the channel is closed. As previously mentioned, addi-

tional materials may be included in the procedure before, during or after the insertion of the spinal fusion implant **10** to aid the natural fusion of the targeted spinal level.

FIG. **10** illustrates a spinal fusion system **105** for performing spinal fusion between adjacent cervical vertebrae, including an exemplary spinal fusion implant **110** and an exemplary cervical insertion instrument **120** provided in accordance with the present invention. The spinal fusion implant **110** may comprise of any suitable non-bone composition having suitable radiolucent characteristics, including but not limited to polymer compositions (e.g. poly-ether-ether-ketone (PEEK) and/or poly-ether-ketone-ketone (PEKK)) or any combination of PEEK and PEKK. The spinal fusion implant **110** may be provided in any number of suitable sizes, such as, by way of example only, a width ranging between 11 to 14 mm, a height ranging between 5 and 12 mm, and a length ranging from 14 and 16 mm.

As will be described in detail below, the cervical insertion instrument **120** is configured to releasably maintain the exemplary cervical fusion implant **110** in the proper orientation for insertion. The cervical fusion implant **110** may be simultaneously introduced into a disc space while locked within the cervical insertion instrument **120** and thereafter released. The exemplary cervical fusion implant **110**, having been deposited in the disc space, effects spinal fusion over time as the natural bone healing process integrates and binds the implant with the adjacent vertebral bodies. This fusion may be facilitated or augmented by introducing or positioning various materials in a space created within or adjacent to the cervical fusion implant **110**. Those materials may be introduced before, during, or after the insertion of the exemplary cervical fusion implant **110**. The additional material may include bone autograft harvested from the patient receiving the spinal fusion implant **10**, one or more additional bone allograft, bio-resorbables or xenograft implants, any number of non-bone implants, and any number of fusion promoting compounds such as bone morphogenic protein.

FIGS. **11-14** depict various embodiments of the exemplary cervical fusion implant **110**. Some common attributes are shared among the various embodiments. More specifically, each cervical fusion implant **110** has a top surface **31**, a bottom surface **33**, lateral sides **14**, a proximal side **22**, and a distal side **16**. In one embodiment, the top and bottom surfaces **31**, **33** are generally parallel. It can be appreciated by one skilled in the art that although the surfaces are generally parallel, that the top **31** and bottom **33** surfaces may be angled with respect to one another to match the natural curve of the spine (i.e. lordosis or kyphosis). By way of example, implants for the cervical or lumbar regions of the spine will have anterior height greater than the posterior height to match the natural lordosis in those regions. Inversely, the implants designed for implantation into the thoracic region will be manufactured with a posterior height greater than the anterior height to match the natural kyophosis in that region. Additionally, the angled surface can aid in overall fit within the vertebral disc space.

The cervical fusion implant **110** preferably includes two receiving apertures **12** which are centrally aligned on the proximal side **22**. The receiving apertures **12** extend inwardly from the proximal side **22** in a generally perpendicular fashion relative to the proximal side **22**. Although shown as having a generally circular cross-section, it will be appreciated that the receiving aperture **12** may be provided having any number of suitable shapes or cross-sections, including but not limited to rectangular or triangular.

The exemplary cervical fusion implant **110** also preferably includes anti-migration features such as anti-migration teeth **6** along the top surface **31** and bottom surface **33**. Additional anti-migration features may include a plurality of proximal anti-migration spikes **68** and/or distal anti-migration spikes **70** integrated vertically through the cervical fusion implant **110**. The anti-migration features increase the friction between the cervical fusion implant **110** and the adjacent contacting surfaces of the vertebral bodies. That friction prohibits migration of the cervical fusion implant **110** during the propagation of natural bony fusion. It should be appreciated by one skilled in the art that such anti-migration teeth **6** can be oriented in a any manner other than generally vertically (as shown) without departing from the scope of the present invention. Moreover, as described above, the spikes **68**, **70** may be constructed from any of a variety of radiopaque materials, including but not limited to a metal, ceramic, and/or polymer material. When the spike elements **68**, **70** are provided having such radiodense characteristics, and the implant **110** is manufactured from a radiolucent material (such as, by way of example only, PEEK and/or PEKK), the spike elements **68**, **70** will be readily observable under X-ray or fluoroscopy such that a surgeon may track the progress of the implant **110** during implantation and/or the placement of the implant **110** after implantation.

The cervical fusion implant **110** has one large fusion aperture **2**, extending in a vertical fashion through the top surface **31** and bottom surface **33** which will function primarily as the avenue for bony fusion between adjacent vertebrae. The cervical fusion implant **110** may have a plurality of visualization apertures **4** which can also serve as an avenue of bony fusion on the lateral sides **14** via cell migration or additional adjuvants. The visualization apertures **4** serve an additional function of allowing a clinician to make visual observations of the degree of bony fusion un-obscured by the lateral side **14** to facilitate further diagnosis and treatment.

FIG. **15** illustrates, by way of example, the orientation of the cervical fusion implant **110** prior to attachment to the cervical insertion instrument **120** by a clinician. One skilled in the art would appreciate that although the current embodiment shows a slidable engagement, various other methods of engagement are contemplated, such as, threadable or hooking features.

FIGS. **16-17** detail the tubular lock member **21** of the exemplary cervical inserter instrument **110**. The tubular lock member **21** includes a central bore **25** dimensioned to receive the proximal end of the elongate fork member **11** therein. The internal dimension of the central bore **25** is smaller than the largest freestanding outer dimension of the taper feature **19**. As a result, the portion of the elongate fork member **11** that may be received by the central bore **25** of the tubular lock member **21** is limited by interference between the distal end of the tubular lock member **21** and the taper feature **19** of the elongate fork member **11**. In the present embodiment, the outer dimension of the threaded feature **13** of the elongate fork member **11** is smaller than the largest outer dimension of the taper feature **19** on the elongate fork member **11**. A thread feature **23** (not shown) at the proximal end of the tubular lock member **21** is situated inside the central bore **25**. The thread feature **23** matches the thread feature **13** on the elongate fork member **11** so that they can be threadably attached to one another. To ease the rotation of the tubular lock member **21** by hand, two semi-circular wings **27** may be provided protruding laterally outward from either side of the tubular lock member **21**. Alternatively, other methods of creating a gripping surface are contemplated including but not limited to knurling or facets.

A clinician can utilize the secured system in either an open or minimally invasive spinal fusion procedure. In either type

of procedure, a working channel is created in a patient that reaches the targeted spinal level. After the creation of that channel, the intervertebral space would be prepared (via known instruments as described above). After preparation, the insertion instrument **120** is used to place a cervical fusion implant **110** into the prepared intervertebral space. Once the cervical fusion implant **110** is inserted into the prepared space, the implant **110** is released from the cervical insertion instrument **120** by retracting the tubular lock member **21** from the elongate fork member **11** by rotating the tubular lock member **21** with respect to the elongate fork member **11** in the opposite direction from that used to initially secure the implant **110**. That motion removes the compressive force on the purchase region **39** between the apertures **12** of the cervical fusion implant **110** and allows the engagement features **17** to be slidably removed from the apertures **12**. After the engagement features **17** are disengaged from the cervical fusion implant **110**, the cervical inserter instrument **120** is removed from the working channel and the channel is closed. As previously mentioned, additional materials may be included in the procedure before, during or after the insertion of the cervical fusion implant **110** to aid the natural fusion of the targeted spinal level.

In order to use the system to perform a spinal fusion procedure, the clinician must first designate the appropriate implant size. After the cervical fusion implant **110** is chosen, the engagement features **17** of the elongate fork member **11** are inserted into the apertures **12** on the implant **110**. At that time the cervical fusion implant **110** and elongate fork member **11** are slidably engaged with one another. Before the clinician can manipulate the combined cervical fusion implant **110** and elongated fork member **11**, they must be releasably secured together. In order to secure the cervical fusion implant **110** onto the elongate fork member **11**, the clinician would next employ the tubular lock member **21**. The clinician would insert the proximal end of the elongate fork member **11** into the central bore **25** of the tubular lock member **21** at its distal end. The tubular lock member **21** would then be advanced over the elongate fork member **11** until the thread feature **13** of that member and the thread feature **23** of the tubular lock member **21** become engaged.

Once engaged, advancement of the tubular lock member requires rotation of the tubular lock member **21** with respect to the elongate fork member **11**. Preferably, after only a small amount of engagement of the thread features the distal end of the tubular lock member **21** would contact the taper feature **19** of the elongate fork member **11**. The tubular lock member **21** would be advanced creating greater interference as the distal end approaches the distal end of the taper feature **19** which has the larger outer dimension. The increasing interference would laterally displace the clamping arms **15** of the elongate fork member **11** towards each other. Since the engagement features **17** of the elongate fork member **11** were initially inserted into the apertures **12** of the exemplary cervical fusion implant **110**, the displacement of the clamping arms **15** would create a compressive force on the purchase region **39** separating the apertures **12** of the exemplary cervical fusion implant **110**. That compressive force allows a clinician to manipulate the system without the exemplary cervical fusion implant **110** becoming disengaged from the cervical inserter instrument **120**.

The enhanced visualization features of the implants **10**, **110** are explained in greater detail with reference to FIGS. **18-23**. FIG. **18** illustrates an implant **10** dimensioned particularly for use in a posterior approach (PLIF) having (by way of example only) a width ranging between 9 and 11 mm, a height ranging between 8 and 14 mm, and a length ranging between 25 and 30 mm. FIG. **19** illustrates the implant **10** of FIG. **18** from a side perspective via as taken via X-ray or fluoroscopy techniques, clearly showing the location of the spike elements **7** and **8** (there is no central spike element **9** as with FIG. **1**) relative to the implant **10** and visualization apertures **4**. FIG. **20** illustrates an implant **10** dimensioned particularly for use in a lateral approach (XLIF™ by NuVasive) having (by way of example only) a width of approximately 18 mm, a height ranging between 8 and 16 mm, and a length ranging between 40 and 45 mm. FIG. **21** illustrates the implant **10** of FIG. **20** from a side perspective via as taken via X-ray or fluoroscopy techniques, clearly showing the location of the spike elements **7**, **8**, **9** relative to the implant **10** and visualization apertures **4**. FIG. **22** illustrates an implant **110** dimensioned particularly for use in the cervical spine having (by way of example only) a width of approximately 11 mm, a height ranging between 5 and 12 mm, and a length of approximately 14 mm. FIG. **23** illustrates the implant **110** of FIG. **22** from a side perspective via as taken via X-ray or fluoroscopy techniques, clearly showing the location of the spike elements **66** relative to the implant **110** and visualization apertures **4**. In this fashion, a surgeon may easily track the progress of the implant **10**, **110** during implantation and/or after implantation by visualizing the spike elements **7**, **8**, **9** and **66**, respectively, under X-ray and/or fluoroscopy according to the present invention.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and are herein described in detail. It should be understood, however, that the description herein of specific embodiments is not intended to limit the invention to the particular forms disclosed, but on the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

For example, while described herein primarily with reference to the lumbar and cervical spinal surgery, it is to be readily appreciated that the spinal fusion implants of the present invention may be suitable for accomplishing fusion in the thoracic spine without departing from the scope of the present invention. Moreover, it is to be readily appreciated that the insertion tools described herein may be employed with implants of any number of suitable constructions, including but not limited to metal, ceramic, plastic or composite.

What is claimed is:

1. A spinal fusion implant positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:

an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space, a distal wall, a proximal wall, a first sidewall, and a second sidewall opposite from the first sidewall, wherein the first sidewall intersects the proximal wall and the distal wall, wherein the second sidewall intersects the proximal wall and the distal wall, wherein the implant defines a straight longitudinal axis extending between the proximal wall and the distal wall, wherein said distal wall, proximal wall, first sidewall, and second sidewall comprise a radiolucent material, wherein the proximal wall includes a tooling aperture axially aligned with the longitudinal axis for releasably mating with an inserter tool;

wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal

wall to a distal end of said distal wall and extending parallel to said longitudinal axis, wherein said implant has a maximum lateral width extending from the first sidewall to the second sidewall along a medial plane that is perpendicular to said longitudinal axis, said implant has a maximum height extending from said upper surface to said lower surface and extending perpendicular to said longitudinal length and said maximum lateral width, wherein said wherein the longitudinal length of the implant is at least two and half times greater than the maximum lateral width, and said maximum lateral width is greater than said maximum height;

at least a first fusion aperture defined by the implant and extending through the implant from said upper surface to said lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space, said first fusion aperture having: a longitudinal aperture length extending parallel to the longitudinal length of said implant and parallel to the longitudinal axis, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width, wherein opposing portions of the first and second sidewalls positioned laterally of the first fusion aperture include outwardly bowed regions that are outwardly bowed away from said longitudinal axis along a direction extending between the proximal wall and distal wall, wherein the outwardly bowed region of the first sidewall is symmetric with the outwardly bowed region of the second sidewall relative to said longitudinal axis; and

means for radiopaque marking said distal wall being positioned in the radiolucent material of said distal wall, means for radiopaque marking said proximal wall being positioned in the radiolucent material of said proximal wall, and a pair of means for radiopaque marking a location of said medial plane in which said maximum lateral width extends, said pair of radiopaque means extending in said medial plane and being positioned in the radiolucent material of said first and second sidewalls.

2. The spinal fusion implant of claim **1**, wherein said anti-migration elements of the upper surface include parallel ridges that extend along the first and second sidewalls, wherein said anti-migration elements of lower surface include parallel ridges along the first and second sidewalls, and wherein the upper and lower surfaces along the proximal wall and the distal wall are free of parallel ridges.

3. The spinal fusion implant of claim **2**, wherein said parallel ridges of said upper surface extend perpendicular to said longitudinal axis.

4. The spinal fusion implant of claim **3**, wherein said parallel ridges of said lower surface extend perpendicular to said longitudinal axis.

5. The spinal fusion implant of claim **2**, wherein two of said parallel ridges of said upper surface extend over a medial support wall extending between the first and second sidewalls, wherein said medial support wall is positioned along said medial plane.

6. The spinal fusion implant of claim **1**, wherein said pair of means for radiopaque marking a location of said medial plane are symmetric to one another relative to a central longitudinal plane extending along the longitudinal axis.

7. The spinal fusion implant of claim **6**, wherein said first sidewall is positioned symmetric with said second sidewall relative to the central longitudinal plane.

8. The spinal fusion implant of claim **7**, wherein said first and second sidewalls each define at least one viewing aperture in communication with the first fusion aperture, wherein said at least one viewing aperture of the first sidewall is symmetric with said at least one viewing aperture of the second sidewall relative to the central longitudinal plane.

9. The spinal fusion implant of claim **1**, wherein the implant comprises the first fusion aperture and a second fusion aperture.

10. The spinal fusion implant of claim **9**, further comprising a medial support wall extending along said medial plane between the first and second sidewalls, wherein the first and second fusion apertures are positioned on opposite sides of a medial support wall.

11. The spinal fusion implant of claim **9**, wherein the first fusion aperture is symmetric with the second fusion aperture relative to the medial plane.

12. The spinal fusion implant of claim **1**, wherein said implant includes four openings defined in said second sidewall, a first pair of said four openings being located in the second sidewall on a first side of said medial plane, and a second pair of said four openings being located in the second sidewall on a second side of said medial plane.

13. The spinal fusion implant of claim **12**, wherein the four openings defined in said second sidewall have the same shape.

14. The spinal fusion implant of claim **1**, wherein said maximum lateral width of said implant is 18 mm.

15. The spinal fusion implant of claim **1**, wherein the first fusion aperture is bisected by a central longitudinal plane extending along said longitudinal axis of the implant and parallel to said height of the implant.

16. The spinal fusion implant of claim **1**, wherein said opposing portions of said first and second sidewalls are outwardly bowed away from one another such that said maximum lateral width of said implant is greater than a maximum lateral width of said distal wall and is greater than a maximum lateral width of said proximal wall.

17. The spinal fusion implant of claim **1**, wherein said proximal wall includes first and second lateral grooves positioned laterally of said tooling aperture, and wherein said tooling aperture and said first and second lateral grooves are configured to releasably mate with a lateral, trans-psoas inserter tool.

18. The spinal fusion implant of claim **1**, wherein said radiolucent material comprises PEEK.

19. The spinal fusion implant of claim **1**, wherein said implant includes at least one visualization aperture extending through at least one of said first sidewall and said second sidewall.

20. The spinal fusion implant of claim **1**, wherein said upper and lower surfaces are parallel to one another.

21. The spinal fusion implant of claim **1**, wherein said upper and lower surfaces are angled relative to one another to approximately correspond to lordosis of a lumbar spine when said implant is positioned within the interbody space.

22. The spinal fusion implant of claim **1**, wherein said first fusion aperture is one of generally rectangular and generally oblong in shape.

23. The spinal fusion implant of claim **1**, wherein the lateral aperture width of said first fusion aperture is more than two time greater than a lateral thickness of said first sidewall and is more than two time greater than a lateral thickness of said second sidewall.

24. The spinal fusion implant of claim **1**, further comprising an osteoinductive material positioned with said first fusion aperture.

25. The spinal fusion implant of claim 1, wherein said pair of means for radiopaque marking a location of said medial plane includes: a first elongate and cylindrical body oriented parallel to said height of the implant and positioned in the first sidewall, and a second elongate and cylindrical body oriented parallel to said height of the implant and positioned in the second sidewall.

26. The spinal fusion implant of claim 1, wherein said means for radiopaque marking said distal wall includes an elongate and cylindrical body oriented parallel to said height of the implant.

27. The spinal fusion implant of claim 1, wherein said means for radiopaque marking said proximal wall includes an elongate and cylindrical body oriented parallel to said height of the implant.

28. The spinal fusion implant of claim 1, wherein said means for radiopaque marking said proximal wall is positioned symmetric with said means for radiopaque marking said distal wall relative to said medial plane.

29. The spinal fusion implant of claim 1, further comprising second means for radiopaque marking said distal wall being positioned in the radiolucent material of said distal wall.

30. The spinal fusion implant of claim 1, further comprising second means for radiopaque marking said proximal wall being positioned in the radiolucent material of said proximal wall.

31. The spinal fusion implant of claim 1, wherein said first and second sidewalls each define at least one viewing aperture in communication with the first fusion aperture wherein said at least one viewing aperture of the first sidewall is symmetric with said at least one viewing aperture of the second sidewall relative to a central longitudinal plane extending along said longitudinal axis of the implant and parallel to said height of the implant.

32. The spinal fusion implant of claim 1, wherein the outwardly bowed regions of the first and second sidewalls extend from the proximal wall to the distal wall such that a convex curvature extends the full length of each of the first and second sidewalls.

33. The spinal fusion implant of claim 1, wherein said pair of means for radiopaque marking a location of said medial plane are positioned between parallel ridges along the first and second sidewalls.

34. The spinal fusion implant of claim 1, wherein said pair of means for radiopaque marking a location of said medial plane comprise rods that are symmetric in shape to one another.

35. The spinal fusion implant of claim 1, wherein said means for radiopaque marking said proximal wall and said means for radiopaque marking said distal wall comprise rods that are symmetric in shape to one another.

36. The spinal fusion implant of claim 1, wherein said height of said implant extends in said medial plane, and wherein said height of said implant is greater than a distal face height of said distal wall and is greater than a proximal face height of said proximal wall.

37. The spinal fusion implant of claim 36, wherein said proximal face height of said proximal wall is greater than said distal face height of said distal wall.

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